Quanterix Launches First pTau-181 Plasma Laboratory Developed Test for Clinical Diagnostic and Research Applications in the U.S.

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Company to present results of validation study at 2022 Alzheimer's Association International Conference

BILLERICA, Mass.--(BUSINESS WIRE)--Jul. 27, 2022-- Quanterix Corporation (NASDAQ: QTRX), a company expanding the limits of exploration with ultrasensitive biomarker detection, today announced the validation of a laboratory developed test (LDT) to quantitatively measure phospho-Tau 181 (pTau-181) in plasma as an aid in diagnostic evaluation of Alzheimer's disease (AD). Quanterix' LDT – the first pTau-181 plasma test released for clinical use in the U.S. – is a quantitative immunoassay intended for the measurement of pTau-181 concentration in human plasma. The test results are intended to be used in adults presenting with cognitive impairment who are being evaluated for AD and must be interpreted in conjunction with other diagnostic tools.

Phospho-tau isoforms are uniquely positioned to anchor efforts to evaluate and diagnose AD pathology. These proteins are specific for AD and can serve to increase the sensitivity and specificity of a test that incorporates less specific blood-based markers of brain health, such as amyloid beta and neurofilament light chain (NfL). A menu of assays covering these markers, including in multiplex formats, has been developed on Quanterix' ultrasensitive platforms to further the Company's goal of helping to advance the understanding of AD and other poorly understood neurological pathologies.

"Quanterix has long been dedicated to arming researchers and pharmaceutical companies with the unparalleled sensitivity to quantify biomarkers in less invasive samples such as blood, so they can advance our understanding and treatment of devastating neurological diseases such as Alzheimer's," said Masoud Toloue, President and CEO, Quanterix Corporation. "Today is a big, new translational step on our mission as our pTau-181 plasma test will aid in the diagnostic evaluation of patients suspected of having Alzheimer's disease. Alongside our pTau-181 clinical test, we also continue to innovate by making markers like NfL available to advance neurodegenerative disease research and therapeutic clinical trials."

The Company will be presenting the results of its LDT validation study at the Alzheimer's Association International Conference (AAIC), taking place in San Diego from July 31 to August 4.

The pTau-181 LDT will be offered through Quanterix' Accelerator Laboratory, a CLIA-licensed and ISO 15189 accredited laboratory fully equipped to support both clinical diagnostic testing and translational research.

To learn more about Quanterix' Simoa® Accelerator Laboratory, visit: https://www.quanterix.com/products-and-services/pharma-services/.

About Quanterix

Quanterix is a company that's digitizing biomarker analysis with the goal of advancing the science of precision health. The company's digital health solution, Simoa, has the potential to change the way in which healthcare is provided today by giving researchers the ability to closely examine the continuum from health to disease. Quanterix' technology is designed to enable much earlier disease detection, better prognoses and enhanced treatment methods to improve the quality of life and longevity of the population for generations to come. The technology is currently being used for research applications in several therapeutic areas, including oncology, neurology, cardiology, inflammation and infectious disease. The company was established in 2007 and is located in Billerica, Massachusetts. For additional information, please visit https://www.quanterix.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements in this news release are based on Quanterix' expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Factors that may cause Quanterix' actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Quanterix' filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein. Except as required by law, Quanterix assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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